

### **REMARKS/ARGUMENTS**

Claims 1-36, 38-118, 128 and 129 are pending in the captioned application. Claims 37 and 116-127 have been cancelled. Claims 1-35 and 41-109 have been withdrawn from consideration. Claims 36, 38-40, 110-115 and 128-129 are under examination and have been rejected. The specification has been amended to delete the embedded hyperlinks and/or other forms of browser-executable code. The claims have been amended. These amendments do not introduce new matter. Applicants respectfully request that these amendments be entered. Applicants submit that the amendments and arguments presented herein clearly place the claims in allowable form. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

#### **Title**

The Examiner states that the title of the invention is not descriptive and requests a new title be provided. In response, Applicants have replaced the original title "Human Genome-Derived Single Exon Nucleic Acid Probes Useful For Gene Expression Analysis Two" with the revised title "A Single Exon Nucleic Acid Microarray Useful For Human Gene Expression Analysis". Applicants respectfully submit that the new title properly describes the invention to which the claims are directed. The objection to the Title should be withdrawn.

### **Claim Objections**

The claims are objected to because the Examiner states that the claims include “sequence defined microarray inventions directed to non-elected and restricted inventions”. In response, the claims have been amended to only include the elected sequence. Accordingly, objections to claims should be withdrawn.

### **Lack of Utility**

Claims 36, 38-40 and 110-129 are rejected under 35 U.S.C. § 101 because, as the Examiner states, “the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well established utility.” With regard to the utility analysis, the Examiner states, “the pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 USC 112, first paragraph”.

Applicants respectfully submit that the claims of the current application are distinct from the hypothetical claims presented in any of the Utility Examination Guidelines. Applicants submit that the closest example Applicants can find is those presented in example 9 of the Utility Examination Guidelines. However, it is Applicants’ belief that the pending claims are distinct from the hypothetical claims in example 9. The claim in example 9 reads: “A cDNA consisting of the sequence set forth in SEQ ID NO: 1”. Pending claims in the current application are not directed to any similar claims.

Claims under examination are directed toward single exon microarrays for measuring human gene expression, comprising spatially-addressable plurality of single exon nucleic acid probes. Applicants submit that probes, microarrays and methods for measuring gene expressed have well established utility in the microarray industry, one of the most rapidly growing fields in the biotechnology industry. Applicants also submit that specific expression of SEQ ID NO.: 13,795 is disclosed in the specification (see Tables 4, 7 – 11), attesting to the usefulness of the probe sequence in measuring expression in a variety of tissues.

Applicants respectfully submit that the claims do not track example 9 or any other examples of the Utility Examination Guidelines. Applicants further submit that the claimed invention has well-established utility in the Biotechnology field. Applicants believe the rejection is in error as it is not addressed to the invention as presently claimed and thus respectfully request that it be withdrawn.

Claims 36, 38-40 and 110-129 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement, based on the corresponding rejection of these claims under 35 U.S.C. § 101 for lack of utility. Because the 35 U.S.C. § 101 rejection is in error for the reasons advanced above, Applicants respectfully request that the rejection for lack of enablement be withdrawn.

**New Matter**

Claims 110-129 are rejected as failing to comply with the written description requirement for containing, what the Examiner describes as NEW MATTER. Applicants respectfully traverse this rejection.

The Examiner states that the “probe characteristics listed in claims 110-129 regarding SEQ ID NO: 13,795 have not been found as filed and therefore are NEW MATTER”. Applicants disagree for the following reasons.

Specifically, Examiner states that “the hybridization of SEQ ID NO: 13,795, under high stringency conditions, to a nucleic acid molecule “expressed in human brain” as claimed in Claim 110 has not been found as filed”. In response, Applicants submit that table 4 clearly demonstrates expression, by hybridization to mRNA, of SEQ ID NO: 13,795 in human brain. Provided this information, Applicants submit that a person of ordinary skill in the art would readily understand that SEQ ID NO: 13,795 is able to hybridize, under high stringency conditions, to a nucleic acid molecule expressed in human brain as claimed in claim 110. Similarly, table 7 shown expression of SEQ ID NO: 13,795 in human fetal liver (claim 111). The same is true for claims 112-115.

With regard to NEW MATTER issues for claims 116-127, Applicants submit that these claims have now been cancelled, formally obviating the rejection.

With regard to the probe content as lacking specific vector, as set forth in claim 128, Applicants submit that claim 128 has been amended to avoid the rejected language. With regard to the probe content as lacking honopolymeric stretches, as set forth in claim

129, Applicants submit that “homopolymeric” is defined in the specification. Applicants direct Examiner’s attention to page 38, lines 8-9, of the specification, where a homopolymeric region is defined “as stretches of 25 or more, typically 30 or more, identical nucleotides”.

Applicants respectfully submit that no NEW MATTER is introduced in the pending claims and request withdrawn of claim rejections under NEW MATTER.

#### **Vagueness and Indefiniteness**

Claims 36, 38-40 and 110-129 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Examiner states that the limitations “complement thereof” and “a fragment of” are vague and indefinite. In response, Applicants have amended claim 36 to require the complementary sequence be a “full complement”, and to require the portions to be “at least 50 contiguous nucleotides”. These amendments are fully supported by the specification, and Applicants believe they meet the 35 U.S.C. § 112, second paragraph requirement. Applicants request that this rejection be withdrawn.

#### **Lack of Written Description**

The pending claims are also rejected under 35 U.S.C. § 112, first paragraph, for failing the written description provision. Applicants respectfully traverse this rejection.

The Examiner states that the “SEQ ID NO: 13,795 meets the written description provisions of 35 USC 112, first paragraph.” However, according to the Examiner, the “claims are directed to encompass gene sequences, sequences that hybridize to SEQ ID NO: 13,795; complements, and fragments. None of these sequences meet the written description provision of 35 USC § 112, first paragraph, as being single exon sequences.”

Applicants submit that Applicants not only described the single exon sequence of SEQ ID NO.: 13,795, but also the genomic sequences containing the single exon sequence (SEQ ID NO.: 88), as well as the polypeptide sequence (SEQ ID NO: 27,454) encoded by SEQ ID NO.: 13,795, respectively. In addition, Applicants amended the claims to require the complementary sequence be a “full complement”, and to require the portions to be “at least 50 contiguous nucleotides” of SEQ ID NO.: 13,795. Applicants submit that these amendments are fully supported by the specification, and they meet the written description requirement of 35 U.S.C. § 112, first paragraph.

In view of the above, Applicants respectfully request that the written description rejection should be withdrawn.

### **Prior Art**

Claims 36, 110-116 and 119-127 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Southern (WO 89/10977). These claims are rejected because the Examiner states that (1) the Southern arrays qualify as a microarray; and (2) Southern

disclosed microarrays with all sequences of a given length, and is inclusive of every sequence of probe as would hybridize to, or match within SEQ ID NO: 13,795.

Applicants traverse this rejection. Applicants submit that Southern does not teach or disclose a single exon microarray for measuring human gene expression, comprising: a spatially-addressable plurality of single exon nucleic acid probes. Applicants further submit that Southern did not disclose a microarray comprising the nucleotide sequence of SEQ ID NO: 13,795, nor the full complement of SEQ ID NO: 13,795, nor a fragment of at least 50 contiguous nucleotides long of SEQ ID NO: 13,795 or the full complement.

Applicants believe the anticipation rejections should be withdrawn.

### **Specification**

Applicants have amended the specification to delete the embedded hyperlinks and/or other forms of browser-executable code, in accordance with the Examiner's suggestions. Applicants respectfully request that the objections to the specification be withdrawn.

Applicants believe the foregoing comprises a full and complete response to the office action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

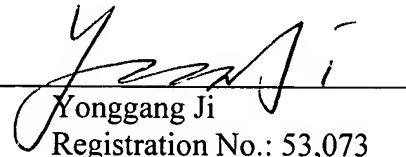
Any questions with respect to the foregoing may be directed to Applicants' undersigned agent at the telephone number listed below.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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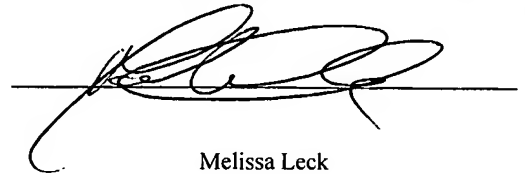
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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on February 28, 2005.

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